

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

<p>Applicant's or agent's file reference see form PCT/ISA/220</p>		<p>Date of mailing (day/month/year) see form PCT/ISA/210 (second sheet)</p>	
<p>International application No. PCT/GB2004/003423</p>	<p>International filing date (day/month/year) 06.08.2004</p>	<p>Priority date (day/month/year) 22.08.2003</p>	
<p>International Patent Classification (IPC) or both national classification and IPC A01N63/02, A01N65/00, A01N45/00, A01N37/38, A01N37/36, A01N35/06, A01N31/16, A01N31/08</p>			
<p>Applicant DANISCO A/S</p>			

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 a sequence listing
 table(s) related to the sequence listing
 - b. format of material:
 in written format
 in computer readable form
 - c. time of filing/furnishing:
 contained in the international application as filed.
 filed together with the international application in computer readable form.
 furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/003423

Box No. II Priority

1. The following document has not been furnished:

- copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)).
 translation of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or
industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	1-67
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-67
Industrial applicability (IA)	Yes: Claims	1-67
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

1) Reference is made to the following documents:

- D1:** INTERNATIONAL JOURNAL OF FOOD MICROBIOLOGY, vol. 68, 2001, pages 141-148, XP002300238
- D2:** FEMS MICROBIOLOGY LETTERS, vol. 183, 2000, pages 191-195, XP002300239
- D3:** LETTERS IN APPLIED MICROBIOLOGY, vol. 29, 1999, pages 166-170, XP001203428
- D4:** LETTERS IN APPLIED MICROBIOLOGY, vol. 36, 2003, pages 448-451, XP009037915
- D5:** FOOD SCI. TECH. INT., vol. 7, no. 6, 2001, pages 487-492, XP009037859
- D6:** INNOVATIVE FOOD SCIENCE AND EMERGING TECHNOLOGIES, vol. 3, no. 1, 2002, pages 55-61, XP009037860
- D7:** JOURNAL OF FOOD SAFETY, vol. 23, 2003, pages 201-217, XP009037908

2) The present application relates to a composition comprising a) an antimicrobial material; and b) an extract obtained or obtainable from a plant of the Labiate family, wherein a) and b) are different, wherein the composition contains phenolic diterpenes in an amount of greater than 1.0 wt.%, and wherein when the antimicrobial material consists of nisin, the composition comprises carvacrol in an amount of less than 0.075 wt.% and carvone in an amount of less than 15 wt.%.

3) Re Item V

3.1 Novelty (Art. 33(2) PCT)

Documents **D1-D6** describe (cf. corresponding abstracts) **synergistic** antimicrobial combinations of nisin and carvacrol, thymol, eugenol, or cinnamic acid.

Document **D7** discloses the antilisterial activity of bacteriocin-producing *Lactobacillus sakei* alone or in combination with food ingredients such as oregano or pepper.

The documents **D1-D7** are not relevant for the novelty of claims 1-63 insofar as the compositions do not contain phenolic diterpenes in an amount of greater than 1.0 wt.%. However, the subject-matter of claims 64-67 cannot be distinguished from that of the prior art since it is not clear (Article 6 PCT) what a composition, a process, a use, or a kit as "substantially" hereinbefore described with reference to any one of the Examples means.

The subject-matter of claims 64-67 cannot therefore be regarded as novel. (it is also to be noted, that the claims must not rely on references to the description, cf. PCT-Guidelines/ISPE 5.10).

3.2 Inventive Step (Art. 33(3) PCT)

All of **D1-D7** are regarded as the closest state of the art. The presently claimed subject-matter differs from **D1-D7** in that the content of phenolic diterpenes in the composition is of at least 1 wt.%. The problem to be solved by the present application may thus be regarded as providing antimicrobial compositions showing **improved** synergistic activity with regard to those of the prior art.

On one hand, it has not been proven that the claimed compositions exhibit a stronger synergistic effect than the compositions of the closest prior art. Thus, it has not been demonstrated that the claimed subject-matter solves the problem posed. On the other hand, the claims are so broadly defined, that it is not believable that the expected effect is achieved within the whole scope of protection, if achieved at all. In the examples, only combinations of nisin and rosemary extracts have been illustrated. Considering the specificity of synergistic effects, it is not reasonable to expect a synergy (even less a synergy stronger than in the prior art) to arise for any antimicrobial material a) as in Claim 1.

The subject-matter of claims 1-67 cannot therefore be regarded as inventive.

3.3 Industrial applicability (Art. 33(4) PCT)

It is acknowledged for the whole set of claims

4) Re Item VII

The references JP 07-03955 & and JP 3042573 and JP 3040282 do not seem to correspond to published Japanese patent applications. They should be corrected (Article 5 PCT).

The document referred to on pg. 6, l. 29-30 followed by the phrase "which article is hereby incorporated by reference", does not appear to be essential to the performance of the invention as required by Article 5 PCT. Thus, this phrase should be deleted (PCT

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International application No.
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Guidelines/ISPE 4.26).

5) Re Item VIII

Claims 31-38, 46, 47, 50, and 51 are unclear (Article 6 PCT) in that they attempt to define the subject-matter in terms of the result to be achieved, which merely amounts to underlying problem, without providing the technical features necessary for achieving this result.

Claims 64-67 rely on references to the description, contrary to Article 6 PCT and the PCT-Guidelines/ISPE 5.10).